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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,607	11/14/2001	Yatindra Prashar	044921-5004	1239

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EXAMINER	
MYERS, CARLA J	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/674,607	Applicant(s) PRASHAR ET AL.	
	Examiner Carla Myers	Art Unit 1634	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 September 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *21 September 2005*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *21,34 and 37-46*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) ~~Paper No(s)~~. filed 3/14/05
13. ☐ Other: _____.

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER

Continuation of 3. NOTE: the amendment to claim 21 to recite "determining which expression profile most closely matches the expression profile prepared from the subject" raises new issues under 35 U.S.C. 112, first and second paragraph. The specification does not provide a definition for this phrase and there is no art recognized definition for this phrase. It is unclear as to what is intended to be encompassed by a closely matched gene expression profile. For instance, it is unclear as to whether such a profile would include only profiles in which the same genes are differentially expressed to the same level, or profiles in which the same total number of genes, of any identity, are differentially expressed, or profiles in which the same genes are differentially expressed at different levels or profiles in which genes of similar function are differentially expressed at the same or different levels. Further, the specification does not provide sufficient guidance as to how to ascertain which profiles most close match those of the subject.

Continuation of 11. does NOT place the application in condition for allowance for the reasons of record in view of the non-entry of the after final amendment. Further, in summary, the response argues that the specification teaches that the genes of interest are modulated under the relevant infection, disease, screening treatment or other experimental conditions and teaches genes whose levels are modulated in a T lymphocyte population form a subject having a sterile inflammatory disease, autoimmune disorder, immunodeficiency disease or T lymphocyte neoplasm. The response points to pages 14 and 45 of the specification in support of this argument. However, the cited teachings in the specification provide only a hypothetical example in which one could use a solid support to compare gene expression levels in subjects which have the noted disorders. A discussion of a method which could be performed to identify genes differentially expressed in these disorders is clearly not equivalent to teaching specific disorders in which specific genes are differentially expressed. As disccussed in the previous Office action, the specification teaches only genes that are up-regulated or down-regulated in activated Jurkat cells as compared to quiescent Jurkat cells, or in activated versus quiescent T lymphocytes. There are no teachings in the specification as to specific genes that are up-regulated or down-regulated in the particular disorders of glomerulonopephritis, or other sterile inflammatory diseases, immunodeficiency disorder, autoimmune disorder, cancer or GVHD. Additionally, the teachings in the specification are limited to differential expression of fragments of genes, rather than full length gene sequences. There is no disclosure in the specification to indicate that the results obtained with these fragments are specific for a particular gene, rather than families of genes or related genes. Further, the claims are not limited to any particular genes, and the proposed amendment to recite that the at least five genes have "expression levels that are modulated under said disease conditions" does not further define the genes in a meaningful manner with respect to their specific structure and function. Applicants assert that the examiner's statements regarding Figures 4 and 5 are "misguided" because the claims do not recite the use of the sequences of Figures 4 and 5. This argument is not persuasive because the claims do not recite any particular sequences, and thereby necessarily include the sequences of Figures 4 and 5 as well as any other undefined sequence. The claims do not appear to include any particular limitations which would exclude these sequences. Applicants cite Heller as teaching that arrays can be used to create gene expression profiles which can then be used to profile a disease. Applicants conclude that Heller thereby teaches how to compare profiles to identify similar gene expression profiles or closely matched profiles. This argument is not persuasive because Heller does not exemplify the diagnosis of a sterile inflammatory disease by detecting a profile which most closely matches another profile. Heller also does not define what constitutes a closely matched profile and does not provide guidance as to how to determine which profiles are similar or closely matched. Heller, as with applicant's specification, provides the experimental details as to how to try to identify particular genes whose expression can be used to diagnose a disease. Heller, as with the present specification, also teaches the methodology previously known in the art, by which one may monitor gene expression patterns from patients and compare these patterns to reference patterns. However, neither Heller nor the present specification teach the identity of specific genes which can be used to diagnose the diseases set forth in the present claims. Again, the claims are not drawn to methods of searching for genes that are associated with diseases by comparing gene expression profiles. Such claims would clearly be obvious over the prior art, particularly the teachings of Heller, which Applicant acknowledges as teaching that gene expression patterns obtained from cDNA microarrays are well suited for profiling any disease.